K002612

C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

SEP 3 2002

BARD

SECTION VI

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Submitter's Name:	C. R. Bard, Inc., Medical Division
Address:	8195 Industrial Blvd. Covington, Georgia 30014
Contact Person:	Donna J. Wilson
Contact Person's Phone:	(770) 784-6135
Contact Person's Fax:	(770) 784-6419
Date of Preparation:	August 23, 2002

B. Device Name:

Trade Name:	Bard® Aegis Foley Catheter with Silver Salts in Hydrogel Coating
Common / Usual Name:	Latex Foley Catheter with Lubricious Coating
Classification Name:	Urological catheter and accessories

C. Predicate Device Name:

Trade Name:	Bardex® Lubricath® Foley Catheter

D. Device Description:

The Bard Aegis Foley Catheter with Silver Salts in Hydrogel Coating is a two-way latex Foley catheter with silver and hydrogel coating.

E. Intended Use:

The Bard Aegis Foley Catheter with Silver Salts in Hydrogel Coating is intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract. Some Foley catheters, especially those with larger (30cc) balloons are used to assist in hemostasis following surgery such as transurethral resection of the prostate.

F. Technological Characteristics Summary:

Table VI-1 provides a tabulated comparison summary of the technological characteristics of the Bard Aegis Foley Catheter with Silver Salts in Hydrogel Coating versus the predicate device.

Table VI-1
Comparison Summary of Technological Characteristics

Component / Characteristic	Bard Aegis Foley Catheter with Silver Salts in Hydrogel Coating (this submission)	Bard Hydrogel-Coated (Bardex® Lubricath®) Foley Catheter (#K910195) (predicate)	Bard Hydrogel-Coated (Bardex® Lubricath®) Foley Catheter (#K910846) (predicate)	Difference
Indications or Intended Use	The Bard Aegis Foley Catheter with Silver Salts in Hydrogel Coating is intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract. Some Foley catheters, especially those with larger (30cc) balloons are used to assist in hemostasis following surgery such as transurethral resection of the prostate.	Bard® Hydrogel-Coated Foley Catheters are intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract. Three-way continuous irrigation Foley Catheters are indicated for use in bladder/urinary tract irrigation. Some Foley catheters, especially those with larger (30cc-75cc) balloons or those with double balooons are used to assist in hemostasis following surgery such as transurethral resection of the prostate. Hydrogel-coated catheters should not be exposed to organic solvents as these may affect coating integrity.	Bard® catheters/drains are intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter/drain through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter/drain, such as a nephrostomy tract. Three-way continuous irrigation Foley Catheters are indicated for use in bladder/urinary tract irrigation. Some Foley catheters, especially those with larger (30cc-75cc) balloons or those with double balooons are used to assist in hemostasis following surgery such as transurethral resection of the prostate. Bard diagnostic catheters are used in the diagnosis of certain urinary disorders and conditions.	No substantial difference for the two-way catheters covered in this 510(k). Note: The 510(k)s covering the Lubricath catheter (#K910195 and #K910846) also contained other models of Foley catheters and/or urethral catheters/drains. Therefore, reference to those catheters is included in the indications statements for these predicate 510(k)s.
Disposable	Yes	Yes	Yes	None
Sterile	Yes	Yes	Yes	None
		Design		
Catheter Base Material	latex	latex	latex	None
French sizes / Balloon sizes Available	8, 10 Fr. / 3cc balloon 12 – 30 Fr. / 5cc balloon 16 – 30 Fr. / 30cc balloon	8-10 Fr/ / 3cc balloon 12 – 30 Fr. / 5cc balloon 14 – 30 Fr. / 30cc balloon	8 and 10 Fr. / 3cc balloon 12 – 30 Fr. / 5cc balloon 14 – 30 Fr. / 30cc balloon	New catheter not available in 14 Fr. With 30cc balloon

	Coating			
Lubricious Coating	Hydrogel hydrophilic polymer with silver salts	Hydrogel hydrophilic polymer	Hydrogel hydrophilic polymer	Addition of silver salts to coating
Catheter Surface Coated	From bifurcation to tip, internal and external including balloon	From bifurcation to tip, internal and external including balloon	From bifurcation to tip, internal and external including balloon	None

G. Performance Data Summary:

The Bard Aegis Foley Catheter with Silver Salts in Hydrogel Coating referenced in this submission is held to the same design, manufacture, and performance specifications as those Foley catheters currently manufactured. Performance and functional testing standards are based on the FDA draft "Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters" dated September 12, 1994.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 2002

Ms. Donna J. Wilson
Director, Regulatory Affairs
C. R. Bard, Inc.
8195 Industrial Blvd.
COVINGTON GA 30014

Re: K002612
Trade/Device Name: Bard® Aegis Foley Catheter with Silver Salts in Hydrogel Coating
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: 78 EZL and KOD
Dated: June 4, 2002
Received: June 6, 2002

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). Specifically, your device is substantially equivalent to Bardex® Lubricath® Foley Catheter with hydrogel coating. Given that you have not provided adequate microbial adherence data, you may not make any claims regarding the effectiveness of the silver salts to reduce microbial adherence to the device or to reduce urinary tract infections in the patients treated with the device. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at one of the following numbers.

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

SECTION I - D

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): #K002612

Device Name: Bard® Aegis Foley Catheter with Silver Salts in Hydrogel Coating

Indications for Use:

The Bard Aegis Foley Catheter with Silver Salts in Hydrogel Coating is intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract. Some Foley catheters, especially those with larger (30cc) balloons are used to assist in hemostasis following surgery such as transurethral resection of the prostate.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1/2/96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K002612